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REMARKS

Claims 1, 2 and 4 remain in this application. Claims 1-4 and 6 are rejected. Claim 3 and 6 are cancelled herein and claim 5 is previously cancelled.

Claims 1 and 4 are amended herein to clarify the invention, to broaden language as deemed appropriate and to address matters of form unrelated to substantive patentability issues. For example, formal matters are attended to that were not addressed by the Examiner and accordingly are considered unrelated to substantive patentability issues.

The changes to claims 1 and 4 do not raise new issues because claim 1 is amended to include the subject matter of claim 6 which was previously considered by the Examiner and claim 4 is amended to remove reference to claim 3 which is canceled in view of the changes to claim 1. As such, entry of this Amendment is respectfully requested.

For the convenience of the Examiner, APPENDIX I is provided herewith having a complete set of pending claims with all amendments effected therein.

Claims 1-4 are rejected under 35 U.S.C. §102(b) as being anticipated by the Eufinger et al. reference and claim 6 is rejected under 35 U.S.C. §103(a) as being unpatentable over the Eufinger et al. reference.

The Examiner's rejections are respectfully traversed.

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Claim 1 is directed to a method for manufacturing a patient-specific implant in which a virtual three-dimensional model of the implant area and the environment thereof is generated and compared to a real medical reference data. From the real medical reference data, a set thereof is selected which is best suited for the patient and a reference model object is formed therefrom.

An important feature of the invention is the manner in which the set of reference data best suited for the patient is selected. Specifically, as described in the specification at page 9, lines 12-26, a plurality of sets of the reference data is first selected and a plurality of reference model objects are formed therefrom which most resemble the patient considering mathematical, functional, medical and aesthetic parameters. That is, characteristics of the patient are considered in selecting a plurality of sets of reference data representing different three-dimensional reference model objects, with one of these reference model objects being ultimately selected as the best suited for the patient by the medical professional(s). For example, four sets of reference data representing four different three-dimensional model objects may be selected in view of the specific parameters (one which is the most suitable considered mathematical parameters, another being the most suitable considering functional parameters, another being the most suitable considering medical parameters and the last being the most suitable considering

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aesthetic parameters) while only one of these will be the final reference model object used to form the patient-specific implant.

Once the reference model object is formed from the best suited set of reference data for the patient, a virtual implant model is generated from the selected reference model object by superimposing the selected reference model object and the virtual three-dimensional model. In order to be superimposed with the virtual three-dimensional model, the selected reference model object is also a three-dimensional model.

Eufinger et al. does not disclose, teach or suggest the selection of a plurality of sets of reference data corresponding to a plurality of reference model objects in consideration of mathematical, functional, medical and aesthetic parameters and selecting one of these reference model objects which is best suited for the patient for generating a virtual implant model by superimposing it with a virtual three-dimensional model.

Eufinger et al. describes forming an endoprosthesis in which data blocks of the actual model of the patient requiring an implant and a single reference model are converted into the data of a CAD free-form surface geometry describing the limiting surfaces of the models through spline and Bezier functions oriented to points of support. The limiting surfaces of the model become coherent, spatial structures whose manipulations carried out locally at the points of support have

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effects on all surfaces adjoining such points of support (see col. 3, lines 21-32).

That is, only some points of the model surrounding the defect area are used and an

interpolation is carried out to determine the other points of the model.

In contrast to the invention, Eufinger et al. does not disclose, teach or

suggest the selection of a plurality of sets of the reference data and the formation

of a corresponding plurality of reference model objects therefrom most resembling

the patient considering mathematical, functional, medical and aesthetic parameters

with one of these plurality of reference model objects being selected as that best

suited for the patient.

Rather, in Eufinger et al., a data block of a single reference model is said

to be available either in a suitable storage medium or acquired

computertomographically from a physically existing reference model (see col. 4,

lines 56-59).

The Examiner's position that it would have been obvious to generate a

plurality of reference model objects in conjunction with the method of Eufinger et

al. is respectfully traversed on the grounds that the Eufinger et al. method is

intentionally performed using only a single reference model (for any number of

different patients) and the use of a plurality of reference model objects will not

provide any benefits. Specifically, since Eufinger et al. relies on the use of only

support points surrounding the defect area and disregards the surface contours

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between the support points, the existence of different surface contours on different

reference model objects will be disregarded by the Eufinger et al. method and thus

the use of multiple reference model objects with different surface contours will be

entirely useless in the Eufinger et al. method.

When applying the Eufinger et al. method, one skilled in the art would

therefore not consider forming multiple reference model objects which differ in

their surface contours as such surface contours have no effect on the formation of

the endoprosthesis in Eufinger et al.

By contrast, since the invention considers all points of the virtual three-

dimensional model and the reference model object, surface contours are important

in the invention and a better, more aesthetically pleasing implant can be created.

The invention is not a situation of a "mere duplication of the essential

working parts of a device" as alleged by the Examiner since there is a novel

comparison step which cannot be considered a duplication of parts. That is, in the

invention, there is a step of "selecting one of the plurality of reference model

objects best suited for the patient". This step cannot be performed in the Eufinger

et al. method in view of the absence of a plurality of reference model objects.

Moreover, the invention involves the step of superimposing the selected

reference model object with the virtual three-dimensional model, which implies that

the reference model object in its entirety is superimposed with the virtual three-

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dimensional model object. That is, all contour and space data (several million points)

are determined two-dimensionally as well as also three-dimensionally and stored in

a computer for further comparison. By contrast, in Eufinger et al., only a few

support points are used, over which an interpolation is carried out, in order to

simulate the defect area and the use of only a portion of the available data leads to

an appreciable loss in quality. This loss in quality is accepted in favor of a decrease

in the computations required by processing fewer points.

In conclusion, Eufinger et al. does not provide any motivation for the

selection of a plurality of reference model objects and indeed, the essence of the

method of Eufinger et al. (the reduction of the reference model object and actual

model to points of support) would eliminate the differences between multiple

reference model objects with common support points so that one skilled in the art

would not even consider using multiple reference model objects when practicing

the method of Eufinger et al. In addition, Eufinger et al. does not perform a

superimposition of an entire virtual three-dimension model to a reference model

object but rather performs a superimposition of points of support only, which is

significantly inferior to the invention and produces lower quality implants.

In view of the foregoing, it is respectfully submitted that the Examiner's

rejections have been overcome and should be removed and that the present

application is now in condition for allowance.

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     In light of the foregoing, the application is now believed to be in proper

form for allowance of all claims and notice to that effect is earnestly solicited.

Please charge any deficiency or credit any overpayment to Deposit Account No.

10-1250.

                                  Respectfully submitted,

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